UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,559	07/17/2003	Dan Peters	2815-0224P	9251

7590 07/08/2004

BIRCH, STEWART, KOLASCH & BIRCH, LLP
P.O. Box 747
Falls Church, VA 22040-0747

EXAMINER	
HUANG, EVELYN MEI	
ART UNIT	**PAPER NUMBER**
1625	

DATE MAILED: 07/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/620,559	PETERS ET AL.	
	Examiner	Art Unit	
	Evelyn Huang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 April 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/450,637.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 15-23 are pending. Claims 1-14 have been canceled according to the preliminary amendment.

Priority

2. The amendment to reference the prior application(s) in the first sentence of the specification is acknowledged.

Claim Rejections - 35 USC § 112

3. The rejection for Claims 19-23 under 35 U.S.C. 112, second paragraph is withdrawn in view of the amendment obviating the rejection.

Claim Rejections - 35 USC § 112(1)

4. The rejection for Claims 15, 17-23 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of the amendment replacing 2-(3-methoxymethyl) with 2-(3-methoxymethyl) thienyl, which has support on page 8, lines 22-23 of the specification.

Claim Rejections - 35 USC § 112(1)

5. The rejection for Claims 19-23 under 35 U.S.C. 112, first paragraph is maintained for reasons of record.

Applicants submit that the present invention is enabled by the specification. Applicants amend claim 19 to recite that the compound acts as an agonist. Applicants also submit herewith Exhibits A, B and C to support enablement for claim 19. Applicants submit that Exhibits A-C disclose assays for determining if a compound has agonistic or

antagonistic activity in treating a particular complication. One of ordinary skill in the art could arrive at the present invention as recited in claim 19 from the disclosure in the specification teaching how to make and use the compound, particularly in conjunction with the knowledge known in the art for how to determine if the compound has agonistic or antagonistic function.

On the contrary, at the time of the invention, the nexus between binding to the acetycholine receptor and the treatment of any or all the diseases recited has not been established as the roles of the nicotinic acetylcholine receptors were still under investigation. The role of nicotinic acetylcholine receptor agonist in the treatment of Alzheimer's disease, depression etc. remains to be determined. Furthermore, the high degree of unpredictability is well recognized in the nicotinic acetylcholine receptor art. A slight modification of the compound would lead to profound changes in its biological activity as evidenced in the very different Kb values exhibited by structurally similar compounds (Olesen, WO 97/11072, PTO-1449, page 12, Table 1). One of ordinary skill in the art would therefore has no basis to extrapolate the results of a tested compound to compounds of dissimilar structure. Moreover, the diseases recited in claim 20 embraces numerous diseases of conflicting conditions arising from different causes via various mechanisms. At present there is no umbrella drug known to treat all the diseases as recited. The diseases requiring an acetylcholine agonist have not been described in the specification.

The specification only describes the procedures for the in vitro nicotinic acetylcholine receptor binding assays and the results for the example compounds on page 17 of the specification. No functional assays or in vivo procedures are described. Although the assays for determining whether a compound is an agonist or an antagonist is known, some experimentation is permitted and every claimed embodiment need not be shown to possess the asserted activity, there should be a showing commensurate in scope with the claims. As stated in In re Cavallito 127, USPQ 202, " where the applicant seeks to obtain a monopoly in exchange for his disclosure of a group of compounds, there should be a disclosure which gives reasonable assurance that all, or substantially all of them are useful....an applicant is not entitled to a claim for a large group of compounds

merely on the basis of a showing that a selected few are useful and a general suggestion of a similar utility in the others". Furthermore, in the instant nicotinic acetylcholine receptor ligand art, where there is a high degree of unpredictability exists, the required disclosure will be greater than for the disclosure of an invention involving a predictable factor such as a mechanical or electrical element. In re Vaeck, 20 USPQ 2d 1438.

In conclusion, in view of the state of the art, the high degree of unpredictability of the art, the absence of specific working examples, the scope of the claims does not commensurate with that of the objective enablement. Insufficient teaching and guidance have not been provided in the specification to enable one of ordinary skill in the art to make and use the invention as claimed without undue experimentation.

Double Patenting

7. The timely filed terminal disclaimer has obviated the obviousness-type double patenting rejection over U.S. Patent No. 6645977.

8. The provisional obviousness-type double patenting rejection over claims 18-20 of copending Application No. 10/380653 is maintained for reasons of record at the present time. Applicants elect to file a terminal disclaimer upon the allowance of the latter application.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The amendment of 'nicotinic acetycholine receptor modulator' in claim 19 to 'nicotinic acetycholine receptor agonist' constitutes new matter since there is no description in the specification that the inventive compound is a nicotinc acetylcholine receptor agonist.

The instant 'disease responsive to the activity of a nicotinic acetylcholine receptor reaches out to as yet unidentified diseases, the description of which is not found in the specification.

Allowable Subject Matter

10. The subject matter of claims 15-18 is allowable.

Audia (6107307) discloses a 3-bicyclic heteroaryl-8-azabicyclo-[3.2.1]-oct-2-enes for inhibition of serotonin reuptake. However, Audia is not prior art since it was filed on 6-7-1999, claiming the benefit of provisional application 60/089951, filed on 6-19-1998, which is after the instant priority date of 5-28-1998.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the

advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 571-272-0686. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecila Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Evelyn Huang
Primary Examiner
Art Unit 1625

***